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From: Judy Fryback, Director
Bureau of Quality Assurance

Guidelines for Using Electronic Signatures in Automated Record-Keeping Systems

As the automation of clinical record systems becomes more prevalent, issues have been raised that are not specifically addressed by current state or federal requirements. The purpose of this memorandum is to provide general guidelines about the use of electronic signatures in automated (computerized) medical record systems.

Providers may maintain individual medical records, with electronic signatures, in a computerized environment as long as the provider has a written policy describing the clinical record and authentication policy(ies) in force. These include, but are not limited to, privacy and confidentiality issues, program oversight, responsibility designation, legal and protective measures to foster data integrity, record reconstruction, and safeguards to prevent unauthorized access. Implementing, at a minimum, the following procedures may alleviate objections to the use of electronic signatures in medical records:

- Delineate those categories of medical, allied health, or other personnel who are authorized to access, modify and authenticate medical records using electronic signatures/computer entry.

- Use a unique ID number, code, password or some other measure (such as a fingerprint/voice activation code) to identify each authorized user of an electronic signature. This ID number, code or password should be confidential and known only to the user, and complex enough so that others cannot employ it.

- Keep a signed statement authorizing that the users electronic signature can only be applied to specific types or sections of the record they have authored. System managers must have the ability to revoke this authorization at any time.

- Establish a system to place responsibility for verifying the accuracy of dictated information. A statement regarding this responsibility could be incorporated into the authorization for use of the electronic signature.

- Include a method for “flagging” records with blanks, incomplete information and/or questions prior to their authentication. Records must be reviewed prior to signing. For systems in which the electronic signature is assigned at the time of transcription, there must be the ability for staff to verify that the record is accurate and that the signature has been properly recorded before it is considered complete.

- Ensure that a security system is established that prohibits changes to a record after it has been authenticated.

- Establish penalties, and enforce them, for anyone who discloses their ID number, code or password to others, or for anyone using an ID number, code, or password without authorization.

At the request of a state surveyor or licensing specialist, a hard copy of a complete medical record must be made available immediately. If the record cannot be produced within 30 minutes of the request, a provider may be cited. Providers must also ensure that sufficient staff are properly trained so that hard copies of the medical record information are available during all operating hours. Backup and retrieval systems must be in place and operational in case of power outages and failures.

REGULATORY REFERENCES

Provider Type	Federal Regulation	WI Administrative Code
Nursing Homes	42CFR 483.75(1) (3) (4) Clinical records.	HSS 132.45(4)(g) 1 HSS 132.45(4)(g) 2.a.and b. Records documentation.
Hospitals	42CFR 482.24(c)(1)(i) and (ii) Medical record services - Content of record.	HSS 124.12(3)(b) HSS 124.14(5) Medical records services - Authentication.
Facilities for the Developmentally Disabled	42CFR483.410(c)(4)&(5) Standard: Legible entries.	HSS 134.47(3)(h)A&B Record entries, signature stamp
Home Health	42CFR 484.48 Condition of Participation: Clinical records. 42CFR 484.48(b) Standard: Protection of records.	HSS 133.21(1) Medical records. Security. HSS 133.21(6) Medical records. Form of entries.
Hospice	42CFR 418.74(a) Standard: Content. 42CFR 418.74(b) Standard: Protection of information.	HSS 131.36(1) Health care record. Documentation and accessibility. HSS 131.36(4)(b) Health care record. Entries.
Community Based Residential Facilities	N\A	HFS 83.18 (1) (2) & (3)
Adult Family Homes	N\A	HSS 89.06(3)(c)5. Service agreement dated and signed by all persons involved in developing the plan. HSS 89.09(1) Resident records access and retention.

If you have questions about these guidelines, please contact the following Bureau staff.

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